

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except §§1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising

of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term “farm” includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to: fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks).

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nonprofit food establishment means a charitable entity that prepares or

serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)).

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter’s immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter’s immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3(b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of